DEPARTMENT OF HEALTH & HUMAN SERVICES

94555d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

January 27, 2004

Harold E. Smith, President
H.S. Seafood, Inc.
2212 Signal Place
San Pedro, CA 90731-7227

W/L 23-04

Dear Mr. Smith:

We inspected your seafood processing facility, located at 2212 Signal Place San Pedro, California on November 12, 13, and 17, 2003 and found that you have serious deviations from the Fish and Fishery Products regulation (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your histamine-forming fishery products are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Fish and Fishery Products regulation through links in FDA's home page at www.fda.gov.

The HACCP deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However your firm does not have a HACCP plan for fresh scombroid forming fishes such as fresh Mahi Mahi, fresh albacore tuna, and fresh Wahoo to control the food safety hazards of histamine receipt and/or formation. As set out in FDA's Fish & Fisheries Product Hazards & Control Guidance, *Third Edition*, FDA believes that histamine formation or a hazard that is reasonable likely to occur in the species listed above.

2. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for fresh Mackerel and your HACCP plan for fresh Sardines do not list the food safety hazard of

histamine formation. In order to establish an effective HACCP plan to control histamine formation, you may wish to refer to Chapter 7 in FDA's Fish & Fisheries Product Hazards & Control Guidance, *Third Edition*. As set out in FDA's Fish & Fisheries Product Hazards & Control Guidance, *Third Edition*, FDA believes that histamine formation or a hazard that is reasonable likely to occur in the species listed above.

3. You must implement the recordkeeping system listed in your HACCP plans, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Receiving and Storage critical control points listed in your HACCP plans for Mackerel and Sardines.

4. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under section 402 of the Act because they may be injurious to health or may have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for fresh Mahi Mahi and Albacore imported from [redacted] FDA import records show that Mahi Mahi and Albacore tuna were imported by your firm on [redacted]

5. You must also implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the Fish and Fishery Products Regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for fresh Mahi Mahi and Albacore imported from [redacted] FDA import records show that Mahi Mahi and Albacore tuna were imported by your firm on [redacted]

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. With regard to your importation of Fish & Fishery products, failure to comply with the import verification requirements in 21 CFR 123 can cause your products to be refused entry into the United States.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as HACCP plans, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

If you have any specific questions regarding this letter, please contact Mr. Robert B. McNab, Compliance Officer at (949) 608-4409. Your written reply should be addressed to:

Director, Compliance Branch
U. S. Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2445

Sincerely,

Alonza E. Cruse
District Director